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510(k) SUMMARY

FEB 12 2003

CureLight's *iClear*

CureLight Ltd.
2 Ha'ilan Street
Northern Industrial Zone, POB 247
Or Akiva 30600, Israel.

Phone: +972 4 6100969
Facsimile: +972 4 6260733

Contact Person: Dr. Yoram Harth

Date Prepared: **January 31, 2003**

Name of Device and Name/Address of Sponsor

iClear Phototherapy Device, Model FGCM0002

CureLight Ltd.
2 Ha'ilan Street
Northern Industrial Zone, POB 247
Or Akiva 30600, Israel

Common or Usual Name

Light Therapy Device

Classification Name

Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology

Predicate Devices

CureLight Ltd.'s ClearLight

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Intended Use

The *iClear* Phototherapy System is intended to provide phototherapeutic light to the body. The *iClear* is generally indicated to treat dermatological conditions. The *iClear* is specifically indicated to treat moderate inflammatory acne vulgaris.

Technological Characteristics

The *iClear* Therapy System is a high intensity lamp intended for the therapy of dermatological disorders such as moderate inflammatory acne vulgaris by emitting visible light in the violet-blue range with fluency of light ranging between 50-200 mW/cm^2. The system includes a spectral band light source with spectral emittance concentrated in the violet/blue spectral band and an optical system for controlling spectra and beam parameters of the light source. It also includes a mechanical fixture for holding the light source at an adjustable distance and direction related to the skin treatment area, and an timer unit to indicate the duration of light treatment.

Substantial Equivalence

The *iClear* has the same intended use indications for use and similar principles of operation, and technological characteristics as the CureLight ClearLight. Thus, *iClear* is substantially equivalent to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2003

Curelight, LTD
c/o Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K030338
Trade/Device Name: *iClear* Phototherapy System, Model FGCM0002
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 31, 2003
Received: January 31, 2003

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K030338

Device Name: ***iClear***

Indications for Use:

The *iClear* Phototherapy System is intended to provide phototherapeutic light to the body. The *iClear* is generally indicated to treat dermatological conditions. The *iClear* is specifically indicated to treat moderate inflammatory acne vulgaris.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)
(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K030338